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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91215699
Party	Plaintiff Boston Scientific Corporation, on behalf of itself and its subsidiaries, Asthmatx, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No.: 85/806,379
Filed: December 19, 2012
For the mark: HOLAIRA
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Boston Scientific Corp. and
Asthmatx, Inc.

Opposers,

v. Opposition No. 91215699

Holaira, Inc.

Applicant.

OPPOSERS' NON-CONFIDENTIAL REPLY BRIEF

Respectfully submitted,

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INTRODUCTION

Opposer cited binding case law for the proposition that when the identification of goods descriptions in the opposed application and registrations of record identify the same goods and are unrestricted, the marketplace reality with respect to classes of consumers and normal channels of trade is irrelevant, and the presumption is that the classes of consumers and channels of trade overlap. [Opp. Br. at 22.] Applicant does not dispute these presumptions nor does it provide any binding case law to the contrary. Applicant also does not dispute that the identification of goods description in its application is unrestricted and that the identification of goods description in Opposers' ALAIR® registration is broad enough to encompass Applicant's goods described in the application. Therefore, Applicant's arguments about consumer sophistication, unrelatedness of the goods, and different channels of trade are irrelevant.

Opposer also cited case law for the proposition that, in the case of intent-to-use applications, an applicant's statements about its intended target consumer or channels of trade are given little, if any consideration, because the applicant's intentions can change. Comparing the arguments made by Applicant in its response with the documents Applicant produced, which are in the record, and the testimony of Dr. Dennis Wahr, Applicant's CEO, demonstrates how selective an intent-to-use applicant can be. Applicant argues [redacted]. Applicant argues its target consumer [redacted]. Applicant argues that HOLAIRA has no meaning, but Applicant's CEO testified the mark connotes providing air to "all the airways, the whole thing, the whole lung." The marketplace reality depicted by Applicant in its response is a fiction. Yet even when the marketplace reality is considered, the record still demonstrates that there is a strong likelihood of confusion between Applicant's HOLAIRA mark and Opposers' ALAIR mark.

ARGUMENT

I. APPLICANT'S CLAIM THAT THE GOODS ARE UNRELATED IN THE REAL WORLD IS FALSE

Applicant claims that the parties' goods cannot "treat the same conditions." [App. Tr. Br. at 38.] Applicant claims its device will treat emphysema and chronic bronchitis, not asthma. [*Id.*] However, Applicant informed [redacted]. [Dkt. No. 14, Ex. 30 at p. 12, Ex. 31 at 4 (identifying COPD as the "initial focus").] Applicant predicted a [redacted] [*Id.* at p. 11.] Applicant's CEO even testified that [redacted] [Dkt. No. 29, Wahr Dep. at 99:1–5, 81:12–82:3.] Accordingly, the "real world" marketplace imagined by Applicant is a fiction because its device could be used to treat asthma.

Opposers' device treats chronic or severe asthma. [Dkt. No. 22, Passafaro Dep. at 12:6–13.] Opposers' have always considered [redacted]. [*Id.* at 12:14–13:2.] Applicant also recognized that it would be natural for [redacted] [Dkt. No. 14, Ex. 28 at p. 8, Ex. 38.] In fact, doctors are already utilizing the ALAIR® device to treat COPD. [Dkt. No. 25, Ex. 74, Shargill Decl. ¶¶ 5, 7.] This is due, in part, to the fact that many patients suffer from both chronic asthma and other obstructive lung diseases. [Dkt. No. 12, Ex. 24; Dkt. No. 22, Passafaro Dep. at 181:9–20, 184:18–24; Dkt. No. 23, Exs. 68, 69, 70; Dkt. No. 25, Ex. 74, Shargill Decl. ¶ 3.] As a result, Applicant's and Opposers' goods can treat the same diseases.

Applicant falsely suggests that the FDA limits the sale of medical devices for particular treatments. [App. Tr. Br. at 39.] The FDA regulates only how a manufacturer markets and labels its medical devices with regard to indications for specific conditions. [Dkt. No. 25, Ex. 74, Shargill Decl. ¶ 6.]. However, the FDA does not limit or interfere with a physician's ability to use a medical device for an off-label use. 21 U.S.C. § 396 (2009); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001).[1] Contrary to Applicant's claim, nothing prevents physicians from directing the use of the parties' goods for non-indicated purposes.

Applicant argued that its goods "function in a different manner" than Opposers' goods. [App. Tr. Br. at 38.] However, minute differences between the function of two parties' goods fail to differentiate the goods. *Fisions Ltd. v. UAD Lab., Inc.*, 219 U.S.P.Q. 661, 662-663 (T.T.A.B. 1983) (disregarding an applicant's argument that its product was administered in tablet form while opposer's goods were distributed through an inhaler).

Applicant argued that its device [redacted] [App. Tr. Br. at 10.] Yet Applicant's own documents state that its device [redacted] [Dkt. No. 14, Ex. 28 at p. 9, Ex. 30 at p. 5, Ex. 34 at pp. 6–9.] Applicant argued that Applicant's device is [redacted] [App. Tr. Brief at 38.] However, medical dictionaries define a bronchus as part of the lung.[2] Applicant argued that its device [redacted] [*Id.*] However, Applicant's goods and Opposers' goods both use RF energy; Applicant has merely added a [redacted] [Dkt. No. 14, Ex. 28 at pp. 8–9, Ex. 30 at 7, Ex. 31 at 16.] Applicant argues that Opposers goods' "reduce the amount of smooth muscle" while Applicant's goods [redacted] [App. Tr. Br. at 38.] Yet Applicant's documents demonstrate that Opposers' goods use "ablation to reduce airway smooth

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[1] "Similarly, "off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." 531 U.S. at 351.

[2] Segen's Medical Dictionary. (2011), defining "bronchus" as "[a]ny of the large airways of the lungs," accessed Nov. 30 2015 from http://medical-dictionary.thefreedictionary.com/bronchus; Mosby's Medical Dictionary, 8th ed. (2009), defining "bronchus" as "any one of several large air passages in the lungs," accessed Nov. 30 2015 from http://medical-dictionary.thefreedictionary.com/bronchus.

muscle" and Applicant's goods likewise use RF energy [redacted] [Dkt. No. 14, Ex. 28 at pp. 8-9.] Both parties' devices utilize an RF generator console, electrode, bronchoscope, and catheter. [*Id.*] Other than the use of a cooling mechanism, Applicant's argument that the goods function differently is a fiction.

Even if these claimed functional differences were true, these distinctions are just like the purported differences cited by the applicant in *Fisions Ltd.*: "fine distinctions without any substantive differences," which fail to differentiate the goods. *Fisions Ltd.*, 219 U.S.P.Q. at 662–63. Regardless of the exact details, the devices are used by the same health care professionals, with the same type of equipment, with the same goal: to reduce or relax the smooth muscle in order to open airways for patients who suffer from obstructive lung diseases.

Finally, Applicant argued that "the devices themselves are dissimilar in appearance." [App. Tr. Br. at 38, n. 12.]. Applicant cites no legal authority for its claim that a party's claimed product configuration or trade dress affects the relatedness of the goods, especially when the application and registrations at issue identify standard character word marks. Further, there is nothing inherently distinctive about the HOLAIRA device that would distinguish it from the ALAIR® device; it is simply a rectangular box. [Dkt. No. 14, Ex. 31 at 14, Ex. 63, Ex. 64.] Accordingly, Applicant's argument lacks any factual or legal basis.

II. APPLICANT'S AND OPPOSERS' CLASSES OF CONSUMERS OVERLAP AND INCLUDE UNSOPHISTICATED CONSUMERS

A. The Parties' Consumers Overlap and Are not Immune to Confusion

The Application includes medical devices, apparatus, and instruments for treating obstructive pulmonary diseases. Applicant admits that its goods will be marketed to interventional pulmonologists. [App. Tr. Br. at 32–33.] Applicant admits that Opposers' goods are marketed to interventional pulmonologists. [*Id.*] Applicant therefore admits that both parties market to interventional pulmonologists, among others.

It is well-established that "even sophisticated consumers are not immune from source confusion." *In re Cook Med. Tech. LLC*, 105 U.S.P.Q.2d 1377, 1383 (T.T.A.B. 2012). This conclusion applies to medical professionals. *Id.*; *Carlisle Chem. Works, Inc. v. Hardman & Holden Ltd.*, 168 U.S.P.Q. 110, 112 (C.C.P.A. 1970). Accordingly, pulmonologists can be confused as to source, especially where, as here, the goods are identical, the channels of trade overlap, and the marks are near homonyms with identical connotations.

B. The Class of Consumers Is not Limited to Interventional Pulmonologists

Applicant incorrectly claims that the only relevant perspective is that of interventional pulmonologists because "physicians are the only ones who can authorize a purchase of these medical devices under federal law." [App. Tr. Br. at 31.] The determination of a likelihood of confusion is not limited solely to the actual purchaser of the goods. *In re Artic Elec. Co., Ltd.*, 220 U.S.P.Q. 836, 837–38 (T.T.A.B. 1983). "Registration should be denied under the Trademark Act when there exists likelihood of confusion, no matter where it occurs in the marketing or sale of similar goods under similar marks." *HRL Assoc. Inc. v. Weiss Assoc. Inc.*, 12 U.S.P.Q.2d 1819, 1822–23 (T.T.A.B. 1989).

Applicant claims that it will market its goods exclusively to interventional pulmonologists. [App. Tr. Br. at 32–33.] However, even before the initiation of this opposition, Applicant identified patients as a target audience. [Dkt. No 14, Ex. 29 at p. 2.] Applicant even created a [redacted] [*Id.* at Ex. 34 at p. 3 and Ex. 35 at p. 1.] The [redacted] [*Id.* at p. 8.] Accordingly, the "real world" imagined in Applicant's brief where patients are not consumers, is a mere fiction, undermined by Applicant's [redacted].

[redacted] Opposers' marketing strategy includes marketing to physicians and patients. [Dkt. No. 22, Passafaro Dep. at 16:13–20, 33:18–34:20, 35:5–23.] Opposers' also market their training services to non-pulmonologists, including anesthesiologists, nurses, and other medical staff. [*Id.* at 13:4–12.] Contrary to Applicant's assertions, these patient materials include prominent use of the ALAIR® mark. [Dkt. No. 14, Ex. 63.] Marketing to patients is a necessary marketing strategy because it is the patient who makes "the ultimate decision as to whether to purchase the treatment offered [with the device]." [Dkt. No. 15, Ex. 78 at p. 6.] Consequently, both [redacted]

Neither the Application nor Opposers' registrations restrict the classes of consumers solely to interventional pulmonologists. [Dkt. No. 12, Ex. 7.] The opinions and beliefs of patients and others within the relevant public affect Opposers' commercial interest in the mark either by conferring an undue benefit upon Applicant or negatively affecting patient demand for treatment with the ALAIR® device. Accordingly, in the registration context and the real world context, the class of consumers for the parties' goods includes unsophisticated members of the relevant public.

Applicant argues that "federal law and the FDA define the 'potential buyers' of the goods at issue." [App. Tr. Br. 36.] However, Applicant does not cite any "federal law" or FDA definition. Regardless, the FDA does not preclude manufacturers from marketing medical devices to patients; it simply limits manufacturers from advertising their devices as treating a disease for which the device has not received an FDA approval. [Dkt. No. 25, Ex. 74, Shargill Decl. ¶ 6.] Opposers and Applicant are and will be free to market directly to patients and describe the devices' ability to improve breathing, open airways, and address symptoms of chronic asthma and COPD respectively. The marketing of either device as improving breathing speaks directly to patients suffering from any obstructive lung disease, but this is especially true for those patients who suffer from both asthma and COPD. [Dkt. No. 12, Ex. 24; Dkt. No. 22, Passafaro Dep. at 181:9–182:3, 184:16–24.] Accordingly, there are no laws or regulations that preclude marketing directly to patients.

The cases relied upon by Applicant to exclude patients as consumers are distinguishable. In *In re Digirad Corp.*, the Board noted that the two products involved "different medical specialties," which is not the case here. 45 U.S.P.Q.2d 1841, 1843 (T.T.A.B. 1998). Further, unlike Applicant's and Opposers' devices, the goods at issue in *Digirad* were not treatment devices marketed to patients, rather, they were diagnostic x-ray and imaging machines that patients had no role in selecting for their treatment. *Id.* Likewise, in *Elec. Design & Sales, Inc. v. Elec. Data Sys. Corp.*, the Federal Circuit expressly recognized this distinction in concluding the consumers were sophisticated because the opposer failed to establish that the ultimate users were aware of the marks and the ultimate users did not influence the actual purchase or sale of the goods. 21 U.S.P.Q.2d 1388, 1392–93 (Fed. Cir. 1992). The First Circuit relied upon similar differences in *Astra Pharm. Prods. Inc. v. Beckman Instruments, Inc.*, noting that the defendant's goods were "used only in the chemistry laboratories of hospitals or research institutions," with no evidence that the parties marketed their goods to patients. 220 U.S.P.Q. 786, 790–791 (1st Cir. 1983).

III. THE CHANNELS OF TRADE OVERLAP IN THE REAL WORLD

Applicant argues that medical devices "are not available on retail store shelves or online," but instead that the purchase process involves the use of a direct sales force of company employees. [App. Tr. Br. at 36.] However the *DuPont* factor regarding the channels of trade includes not only how a product is sold, but how a product is marketed and advertised. *Miles Lab., Inc. v. Int'l Diagnostic Tech., Inc.*, 220 U.S.P.Q. 438, 445 (T.T.A.B. 1983); *In re 1st USA Realty Prof'ls, Inc.*, 84 U.S.P.Q. 1581, 1587 (T.T.A.B. 2007) (relying on similar advertising and promotion channels, including direct mailings, internet promotion, print ads, television, etc.).

Applicant admits that it will market its goods through a direct sales force. [App. Tr. Brief at 36.] Like Applicant, Opposers' channels of trade include a direct sales force. [Dkt. No. 22, Passafaro Dep. at 33:18–35:23.] Accordingly, Applicant's and Opposers' devices utilize the same channels of trade, weighing in favor of a finding of a likelihood of confusion.

Applicant argues that the buying process will alleviate any potential confusion because the parties' products "are sold by sales representatives known to work for separate medical device manufacturers." [App. Tr. Br. at 34.] Applicant does not specify which consumers (*e.g.*, hospital administrators, physicians, nursing staff, or patients) are expected to know or understand the distinction, nor does Applicant specify how each relevant consumer would know. Applicant does not specify what facts, if any, support its conclusion that all sales representatives are somehow "known to work for separate medical device manufacturers." Applicant can only rely on unsupported assumptions because Applicant has not yet commercialized its use of the HOLAIRA mark. [Dkt. No. 29, Wahr Dep. at 59:24–60:10.] Accordingly, Applicant's purported restrictions regarding channels fails to diminish the likelihood of confusion, even in the purported and irrelevant "real world" marketplace created by Applicant.

Applicant's suggestion that it will only market its goods **exclusively** through a direct sales force, [App. Tr. Brief at 36.], directly contradicts sworn testimony from Applicant's CEO that its marketing channels will include advertising journals and the internet. [Dkt. No. 29, Wahr

Dep. at 64:4–13.] Applicant also intends to promote its goods through trade shows. [*Id.* at 54:4–20.] Applicant's claimed and irrelevant limitation of channels of trade is therefore a fiction.

Like Applicant, Opposers' channels of trade includes journals, and the internet. [Dkt. No. 22, Passafaro Dep. at 33:18–35:23.] Opposers' channels of trade also include advertising and marketing through direct mailings, printed ads, and television. [*Id.* at 33:18–34:20.] Opposers' channels of trade also include trade shows and patient fairs. [*Id.* at 33:18–34:20, 46:6–47:–14; Dkt. No. 16, Ex. 78 at pp. 5-7.] Accordingly, Applicant's goods travel in overlapping channels of trade with Opposers' medical devices, including in channels other than a direct sales force.

Finally, Applicant's registered rights would extend to any and all future channels of trade because the purported restriction is not identified in the Application. *In re Star Pharm., Inc.* 221 U.S.P.Q. 84, 85 (T.T.A.B. 1984) (disregarding claim of customer sophistication because "there is no assurance that today's 'prescription only' preparations may not become available over the counter tomorrow"). Accordingly, even if Applicant's claimed restriction were accurate, it would be insufficient to avoid a likelihood of confusion.

IV. APPLICANT'S PROPOSED HOLAIRA MARK CREATES A SIMILAR OVERALL COMMERCIAL IMPRESSION TO THE ALAIR® MARK

A. Applicant's Criticism of Dr. Nunberg's Report Is Unfounded

Applicant incorrectly claims that the Board should give Dr. Nunberg's opinion no weight. The cases relied upon by Applicant recognize that linguistic expert testimony is admissible and relevant. *Edwards Lifescience Corp. v. VigiLanz Corp.*, 94 U.S.P.Q.2d 1399, 1401 (T.T.A.B. 2001). The cases simply stand for the proposition that the Board will make its own ultimate conclusion based on the relevant evidence before it—which includes testimony of linguistic experts. *Id.*; *see also Research in Motion Ltd. v. Defining Presence Mktg. Grp., Inc. and Axel Ltd. Co.*, 102 U.S.P.Q.2d 1187, 1193 (T.T.A.B. 2012).

Applicant also argues that Dr. Nunberg's testimony constitutes an impermissible legal opinion. However, the similarity of the marks, including the similarity of sound, is a question of fact. *Bose Corp. v. QSC Audio Prods.*, 63 U.S.P.Q.2d 1303, 130 (Fed. Cir. 2002). Accordingly, Dr. Nunberg's testimony does not constitute a legal opinion.

Applicant further criticizes Dr. Nunberg's testimony purportedly because his expert opinion "fail[s] to address necessary context and the attributes of the relevant consumers." However, the legal authority cited by Applicant does not support its position. Those cases merely hold that the *meaning* of the marks should be considered in the commercial context; they do not require that the *pronunciation* of the mark be considered in the commercial context if the evidence of record establishes that the commercial context contributes to the meaning of the marks. *Ferro Corp. v. Nicofibers, Inc.*, 196 U.S.P.Q. 41, 45 (T.T.A.B. 1977) ("[t]he words 'UNIFORM' and 'CONFORM', as revealed by this record, have and project to the trade distinctly different meanings.") Even if Applicant's criticism was supported by its own case law, it has failed to present any evidence or argument as to how the commercial context of the mark could affect the pronunciation of the marks. Accordingly, its bald assertion is baseless in view of the record.

Last, Applicant falsely claims that "Dr. Nunberg fails to account for the different number of syllables in the two marks." In fact, Dr. Nunberg specifically stated that "in conversational speech the names HOLAIRA and ALAIR are actually near-homonyms, distinguished only by the presence of the unstressed final /e/[.]" Dkt. No. 13, Ex. 27 Nunberg ¶ 17.] Dr. Nunberg specifically addressed the extra syllable, but identified specific reasons why the additional syllable does not distinguish the marks, namely, because it is an unstressed syllable located in the final position. [*Id.*] Dr. Nunberg testified that such syllables are "often difficult to discern" providing the example comparison of "I spoke to Donna and Mary" versus "I spoke to Don and Mary." [*Id.*] Such a minute difference fails to distinguish the marks because it "is discernible only if the mark is perfectly pronounced." *In re Energy Telecommc'ns & Elec. Assoc.*, 222 U.S.P.Q. 350, 352 (T.T.A.B. 1983). Therefore, each of Applicant's criticisms of Dr. Nunberg's report are unfounded.

B. Applicant Fails to Present Evidence to Contradict Dr. Nunberg's Conclusion

Rather than consider the pronunciation as a whole, Applicant reduces the similarity in sounds factor to a mere exercise in counting syllables. Applicant relies upon *Parfums de Couer, Ltd. v. Lazarus* to conclude that the addition of a single syllable can distinguish two otherwise similar marks. Applicant's reliance on this decision is misplaced. In that decision, the Board compared the mark BOD MAN with the mark BODYMAN and Design. 83 U.S.P.Q.2d 1012 (T.T.A.B. 2007). However, the Board found the marks to be similar in sound, but concluded the similarity in sound was outweighed because "applicant's mark includes a prominent design element, and it is intended to be used for an animated television series." *Id.* The Board reasoned that the design reinforced the commercial impression that BODY MAN referenced a super hero consisting of a body and that this commercial impression would be conveyed in the advertising because the services identified in the application were providing an animated cartoon television program, where the design element would be prominently seen by consumers. *Id* at 1016–17. Also, the goods and services were highly unrelated, namely, perfume and providing an animated television series. Accordingly, the *Parfums de Couer* decision is therefore distinguishable.

Applicant also argues that it intends for the mark to be pronounced as "whole–air–ah." [App. Tr. Br. at 25.] Yet Applicant does not disagree there is no single correct pronunciation of the mark. [Opp. Tr. Br. at 24.] In fact, Applicant itself [redacted]

[redacted]

[Dkt. No. 14, Ex. 41.] Accordingly, Applicant's argument lacks any legal or factual basis.

Applicant also presents no facts that contradict Dr. Nunberg's analysis. First, Applicant does not disagree with Dr. Nunberg's testimony that the stressed syllable in the HOLAIRA mark is the LAIR syllable. [Dkt. No. 13, Ex. 27 Nunberg ¶ 13.] Second, Applicant does not disagree that the initial H is an aspirated sound which is not normally pronounced in English, such as honest, hour, and honor. [Dkt. No. 13, Ex. 27, Nunberg ¶ 15.] This is especially true for Spanish speakers, or individuals who mistakenly assume that the HOLAIRA may be pronounced similar to a Spanish word such as "hola." [*Id.* ¶ 18.] Opposers received many requests for Spanish language materials and consequently produced a patient brochure and testimonial in Spanish. [Dkt. No. 22, Passafaro Dep. at 53:18–54:5.] Third, Applicant does not disagree the rules of English also do not allow the final 'a' syllable to be stressed. [*Id.* ¶ 13.] The record contains no evidence to contradict Dr. Nunberg's conclusion that the HOLAIRA and ALAIR® marks would naturally be pronounced as "near homonyms." [*Id.* ¶ 17.] At a minimum, the evidence establishes that such a pronunciation would be reasonable.

Applicant also mischaracterizes Opposers' evidence of overall similarity as a claim that "some of the letters in HOLAIRA could be used to spell ALAIR." [App. Tr. Br. at 26, n. 8.] Instead, Opposers argued that the marks are pronounced as near homonyms, with the only visual similarity being the use of the letters HO. [Opp. Tr. Br. at 26.] A nearly identical argument was rejected by the C.C.P.A. in *Carlisle Chem. Works*, 168 U.S.P.Q. at 110. There the C.C.P.A. reversed the Board's decision, finding the marks COZIRC and ZIRCO to be confusingly similar. *Id.*at 112–13. The Board reasoned that the applicant "had a wide range of potential marks from which to make a selection and chose one which contains the essentially identical syllables of [the opposer's] mark, arranged in reverse order." *Id.* at 113. Because the HOLAIRA and ALAIR marks contain essentially identical syllables, the marks create similar overall commercial impressions, just as in *Carlisle.*

C. Applicant Ignores the Similarities in the Connotation of the Marks

Applicant argued that the ALAIR® and HOLAIRA marks are coined terms with no generally understood meaning. [App. Tr. Br. at 28.] Contrary to Applicant's assertions, Applicant admitted that its HOLAIRA mark is derived from a combination of WHOLE and AIR. [Wahr Dep. at 40:6–13; Dkt. No. 14, Ex. 33 at p. 11.] Applicant's ALAIR® mark is derived from a combination of ALL and AIR. The terms 'all' and 'whole' are synonyms. [Dkt. No. 12, Exs. 8, 9, 12, 13.] Applicant even argues in its brief that Applicant [redacted] [*Id.*] Indeed, when describing its HOLAIRA mark Applicant's own CEO [redacted] (emphasis added) [Dkt. No. 29, Wahr Dep. at 40:6–13.] Accordingly, even though the marks are coined terms, they connote identical meanings.

Applicant argues that there is no need to analyze the possible connotations of the marks simply because the marks "do not appear in any dictionaries." [App. Tr. Brief at 28] However, even coined terms still have connotations, even if they do not have an exact dictionary definition. *See San Fernando Elec. Mfg. Co. v. JFD Elec. Components Corp.*, 196 USPQ 1, 3 (C.C.P.A. 1977) (analyzing the connotations of two coined terms). Indeed, Applicant implicitly acknowledges that its assertion is wrong by arguing that consumers will understand both parties' as connoting a meaning of "air." [App. Tr. Br. at 26.] If consumers could not discern any meaning from a coined term, they could never identify the marks as incorporating the AIR element. Accordingly, the fact that HOLAIRA and ALAIR® have similar connotations weighs in favor of a finding that the marks create similar overall commercial impressions.

In fact, Applicant's argument actually enhances the likelihood of confusion. Where two marks are coined terms without defined meaning, confusion is more likely. *E.I. du Pont de Nemours and Co. v. Yoshida Int'l Inc.*, 185 U.S.P.Q. 597, 604 (E.D.N.Y. 1974) (finding TEFLON and EFLON confusingly similar). Consumers do not remember unfamiliar marks precisely as they would if the marks consisted solely of familiar words with precise definitions. *Id.* Accordingly, Applicant's admission actually enhances the likelihood of confusion.

D. Use of Corporate Names and House Marks Cannot Distinguish the Marks as a Matter of Law

Applicant suggests that Opposers' use of its corporate name and the BRONCHIAL THERMOPLASTY treatment name decreases the overall likelihood of confusion. [App. Tr. Br. at 11–12, 33–34, 41–42.] Additional terms that appear alongside registered or applied-for marks cannot distinguish the marks unless those additional marks are also included in the relevant application or registrations. *In re Shell Oil Co.*, 26 U.S.P.Q.2d 1688, 1691 (Fed. Cir. 1993). Opposers' registrations identify only the ALAIR® mark; they do not include a corporate name or other mark. [Dkt. No. 12, Exs. 1, 3.] The Application includes only the claimed HOLAIRA mark. Therefore Applicant cannot rely on any additional terms to distinguish the marks.

V. APPLICANT HAS FAILED TO ESTABLISH THAT THE ALAIR® MARK IS WEAK

A. The Third-Party Registrations Do not Establish that ALAIR® Is Weak

Applicant asserts that Opposers' ALAIR® mark is weak based upon third-party registrations. [App. Tr. Br. at 42.] However, third-party registrations do not weaken the strength of the senior user's mark when the registrations involve goods or services outside of the relevant market. *In re Vroman Foods, Inc.*, 224 U.S.P.Q. 242, 244 (T.T.A.B. 1984) (disregarding third-party marks in connection with food products where those food products were not as similar to opposer's chewing gum as was applicant's ice cream). The relevant goods identified in Applicant's Application and Opposers' registrations are identical and directly competitive; none of the third-party registrations identified by Applicant involve related goods. Opposers defined the relevant market as medical devices for the treatment of obstructive lung diseases. [Dkt. No. 22, Passafaro Dep. at 17:13–19.] Applicant did not object to this market definition. In fact, Opposers and Applicant both agreed that pharmaceuticals do not compete with the parties' medical devices and that the medical devices and pharmaceuticals are not marketed in the same channels of trade. [Dkt. No. 29, Wahr Dep. at 107:20–108:23; Dkt. No. 22, Passafaro Dep. at 166:15–23, 172:11–19.]

Applicant's argument attempts to broaden the relevant market to all goods with any connection to the respiratory system, regardless of purpose, function, condition, or symptoms. None of Applicant's third-party marks fall within the relevant market definition. [Dkt. No. 17, Exs. 1–76.] Out of the 44 registrations, 23 involve pharmaceuticals, which do not compete with the parties' medical devices, and therefore do not affect the strength of the ALAIR® mark. [Dkt. No. 17, Exs. 1–3, 5, 7, 9, 15, 18, 19, 21–24, 26–28, 34, 36, 40–44.] Seals for sleep apnea masks do not compete with the parties' medical devices and therefore do not affect the strength of the ALAIR® mark. [*Id.*, Ex. 10.] Medical air compressors do not compete with the parties' medical devices and therefore do not affect the strength of the ALAIR® mark. [*Id.* at 37.] Oxygen therapy and oxygen concentration devices do not treat obstructive lung disease and do not compete with the parties' medical devices and therefore do not affect the strength of the

ALAIR® mark. [*Id.*, Exs. 38, 39.] None of the third-party marks are registered in connection with goods in the relevant market and therefore none of the registrations affect the strength of the ALAIR® mark.

Further, even if some consideration is given to these registrations, none of the third-party marks identified by Applicant involve marks that are as similar to Opposers' ALAIR® mark as Applicant's claimed HOLAIRA mark. In order to establish that a senior user's mark is weak, third-party marks must be as "close to the marks at issue in the [present] case." *Midwestern Pet Foods, Inc.*, 103 U.S.P.Q.2d at 1440–41. Out of all of the marks identified by Applicant, there are only seven marks that incorporate the LAIR element: CIRCULAIRE, SINGULAIR, VENTILAIR, VITALAIRE, PILAIRO, XOLAIR, and NEBULAIR. [Dkt. No. 17, Exs. 1–76.] None of these marks are as phonetically similar as ALAIR® and HOLAIRA, which can be pronounced as near homonyms. Further, none of these marks create as similar of a commercial impression of providing air to the whole lung or all of the lung. *See Specialty Brands, Inc. v. Coffee Bean Distribs., Inc.*, 223 U.S.P.Q. 1281, 1285 (Fed. Cir. 1984) ("None of these marks has a 'SPICE (place)' format or conveys a commercial impression similar to that projected by the SPICE ISLANDS mark, and these third-party registrations are of significantly greater difference from SPICE VALLEY and SPICE ISLANDS than either of these two marks from each other."). Because none of third-party marks are as similar to Opposers' ALAIR® mark as is the HOLAIRA mark, these third-party marks do not weaken Opposers' rights in its ALAIR® mark.

Each of the cases relied upon by Applicant is distinguishable. In *Juice Generation, Inc. v. GS Enters.*, the opposer's mark, the applicant's mark, and the third-party marks all shared the terms PEACE and LOVE. 115 U.S.P.Q.2d 1671 (Fed. Cir. 2015). In *Jack Wolfskin Ausrustung Fur Draussen GMBH & Co. KGAA v. New Millennium Sports, S.L.U.*, the applicant's mark, opposer's mark, and the third-party marks all included a design of paw prints. 116 U.S.P.Q.2d 1129 (Fed. Cir. 2014) (designs of paw prints). Unlike the foregoing cases, none of the third-party marks identified by Applicant are as phonetically similar as ALAIR® and HOLAIRA and therefore are insufficient to establish that Opposers' ALAIR® mark is weak.

B. Applicant's Evidence Does Not Establish Extensive Use by Third-Parties

"The probative value of third-party trademarks depends entirely upon their usage." *Palm Bay Imports, Inc. v. Veuve Clicquot Ponsardin Maison Fondee En 1772*, 73 U.S.P.Q.2d 1689, 1693 (Fed. Cir. 2005). The mere existence of a third-party mark is insufficient to establish weakness when there is no evidence to demonstrate the extent to which the consuming public is aware of the use of the third-party marks. *Id.* at 1693; *Han Beauty, Inc. v. Alberto-Culver Co.*, 57 U.S.P.Q.2d 1557, 1561 (Fed. Cir. 2001) (where the "record includes no evidence about the extent of [third-party] uses ... [t]he probative value of this evidence is thus minimal."). Here, the only evidence produced by Applicant is a handful of website printouts for some of the marks, which establishes nothing more than the fact that the word is on a website. None of this evidence establishes that the goods are available for sale, whether any sales have been made, whether any sales were made in the U.S., or whether a single consumer ever encountered the web page.

Further, the purported evidence does not demonstrate third-party marks used in U.S. interstate commerce. Exhibits 48, 55, and 61 are merely Google search engine result pages. [Dkt. No. 18.] Exhibit 66 is an abstract from a medical journal. [*Id.*] Exhibit 54 is an Italian website that provides no indication regarding use of the mark in the U.S. [*Id.*] Exhibit 53 is an excerpt from a message board for a U.K. cycling charity. Exhibits 60 and 71 are press releases regarding recent approval of products for marketing in Denmark and the E.U. respectively. [*Id.*] Exhibit 67 is a press release regarding an award given to an inhaler by the European Aluminium [*sic*] Association. [*Id.*] Exhibit 72 is an excerpt from a design company discussing its role in developing a computer processor for a product. [*Id.*]

Moreover, Applicant's claim that 44 registrations share the "key AIR element" is misleading. A number of the registrations identify the same mark, owned by the same party. There are only 33 unique marks identified in the evidence. One of the registrations has been cancelled for failure to file a Declaration of Use.[1] Of the 44 registrations, 13 are registrations based on Section 44(e) or 66(a), for which no evidence of use has been submitted to the Trademark Office. [Dkt. No. 18, Exs. 6, 7, 9, 15, 19, 24, 25, 35, 38, 39, 40, 41, and 44.]

In sum, there are only 22 unique marks registered based on use in commerce. Only four include the LAIR letter string: SINGULAIR, CIRCULAIRE, VENTILAIR, and XOLAIR. None of these marks are registered in connection with medical devices, let alone competitive medical devices for lung diseases. [Dkt. No. 29, Wahr Dep. at 107:20–108:23; Dkt. No. 22, Passafaro Dep. at 166:15–23, 172:11–19.] None of these marks share the same level of phonetic similarities and similarities in meaning as the ALAIR® and HOLAIRA marks. Accordingly, Applicant's evidence of third-party use fails to establish that Opposers' ALAIR® mark is weak.

C. Applicant's Reliance on The Stratagem Presentation is Misplaced

Applicant incorrectly claims that [redacted] relying upon a third-party consultant's presentation provided to Opposers in 2009. In its brief, Applicant mischaracterizes Stratagem as "experts." Stratagem was a "marketing communications agency." [Dkt. No. 22, Passafaro Tr. at 142:2–5.] Stratagem has

[1] Further, Registration No. 3,547,148 for the NUAIR mark identified in Exhibit 23 has since been cancelled for failure to file a Section 71 Declaration of Use.

not been qualified as an expert nor is there evidence in the record to establish that Stratagem has any expertise in the health care or medical device industry.

Opposers expressly disagreed with the [redacted]. [*Id.* at 175:16–21.] Based upon Opposers own knowledge of the industry, Opposers concluded that ALAIR® was a strong mark and chose to move forward with the ALAIR® mark. [*Id.* at 175:25–177:9.] [redacted], made prior to the occurrence of a single sale or advertisement, has no bearing on the current strength of the ALAIR® mark. Applicant's misleading characterization of such statements as "admissions" has no basis in law or fact.

To the extent the Board gives any probative weight to the third-party arguments, any conceptual weakness has since been strengthened by the commercial success of the ALAIR® mark. The Stratagem report was created in 2009. [*Id.* at 146:10–18; 154:2–8.] At that time, the FDA had not yet approved Opposers' medical device for commercial use, Opposers had not commercially sold a device, and Opposers were legally precluded from advertising the goods. [*Id.*] Since that time, Opposers have generated more than [redacted] and spent more than [redacted]. [Opp. Tr. Br. at 32; Dkt. No. 22, Passafaro Dep. Exs. 1, 2, 8.] Accordingly, the consultant's conclusions and recommendations do not reflect the current strength of Opposers' ALAIR® mark.

VI. THE *DUPONT* FACTOR REGARDING ACTUAL CONFUSION IS NEUTRAL

Applicant argued that the absence of any evidence of actual confusion in the record weighs in Applicant's favor. However, the absence of actual confusion has little probative value, if any, unless there has been an appreciable period of overlapping use of the marks in the same geographic area. *Top Tobacco LP v. North Atlantic Operating Co.*, 101 U.S.P.Q.2d 1163, 1174 (T.T.A.B. 2011).

Applicant did not use its mark in any way prior to filing its intent-to-use application on Dec. 19, 2012. [Dkt. No. 12, Ex. 6.] Applicant's product will not even be approved [redacted]. [Dkt. No. 29, Wahr Dep. at 94:13–17.] Applicant only claims that it made use of the HOLAIRA mark as a trade name on its building, on business cards, and in business presentations. [Dkt. No. 29, Wahr Dep. at 53:14–58:2.] There are no clinical sites in the U.S. [*Id.* at 56:24–57:2.] Applicant therefore has not yet made trademark use in commerce in connection with the medical devices identified in the Application. In fact, Applicant admitted that it has only publicly presented its company once, in Munich, Germany, in the fall of 2014. [*Id.* at 54:4–14.] Accordingly, there has been insufficient opportunity for confusion to arise. Therefore, this factor is neutral.

VII. APPLICANT HAS NOT PRESENTED EVIDENCE OF GOOD FAITH INTENT

Applicant argues that there are "no facts" to support a claim of bad faith and that mere knowledge "in and of itself" is insufficient to establish bad faith. However, the record establishes far more than knowledge. [Opp. Tr. Brief at 33–34.] Applicant's documents establish that Applicant [redacted] [Dkt. No. 14, Ex. 41.] Accordingly, the documents establish a bad faith intent. The burden shifts to Applicant to identify documents in the record to rebut these facts. Applicant has failed to do so and, therefore, the intent factor weighs in Opposers' favor.

CONCLUSION

Applicant ignores black letter law regarding the necessity to evaluate a likelihood of confusion in the context of the goods and services identified in the application and Opposers' registrations. As set forth in the Application and Opposers' registrations, Applicant's Goods and Opposers' Goods are identical, directly competitive, will travel in overlapping channels of trade, and will appeal to the same classes of consumers. Further, Applicant wholly ignores the likelihood of confusion between the Application and Opposers' Reg. No. 3,380,080 for the ALAIR® mark in connection with training and teaching services for pulmonary medical devices.

Even if the complete absence of restrictions in the application were improperly ignored, a likelihood of confusion still exists in the real world market, too. Applicant's claimed real world marketplace is a mere fiction, contradicted by Applicant's own documents and testimony. The parties' goods have the capability to directly compete, are marketed to identical consumers, in identical channels of trade, and are marketed to unsophisticated individual patients.

As the junior user, Applicant had the opportunity and duty to avoid a likelihood of confusion with senior users. Applicant identified Applicant's and Opposers' devices to be directly competitive and knew the channels of trade and classes of consumers would directly overlap. The choice of HOLAIRA even raised internal red flags, prompting Applicant to "double check" whether the HOLAIRA mark was too close to Opposers' ALAIR mark. Yet Applicant chose to move forward with the HOLAIRA mark.

Accordingly, the record establishes the (1) similarity of the marks, (2) relatedness of the goods, (3) channels of trade, (4) sophistication of consumers, and (5) strength of the senior mark factors all weigh in favor of a finding of a likelihood of confusion. The factor regarding actual confusion is neutral. Accordingly, the evidence of record establishes by a preponderance that Applicant's proposed HOLAIRA mark is likely to cause confusion with Opposers' ALAIR® mark. Therefore, Opposers respectfully request that the Board sustain this opposition and deny registration of Applicant's HOLAIRA mark.

APPENDIX TO OPPOSERS' REPLY BRIEF

Non-U.S. Patent Quarterly Decisions

1. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)

121 S.Ct. 1012
Supreme Court of the United States

BUCKMAN COMPANY, Petitioner,
v.
PLAINTIFFS' LEGAL COMMITTEE.

No. 98-1768. | Argued Dec. 4, 2000. | Decided Feb. 21, 2001.

Patients claiming to have suffered injuries from implantation of orthopedic bone screws into pedicles of their spines brought suit alleging that regulatory consultant to manufacturer of screws made fraudulent representations to the Food and Drug Administration (FDA) in course of obtaining approval to market screws that were serious enough to have played substantial role in events which resulted in their injuries. The United States District Court for the Eastern District of Pennsylvania dismissed state law "fraud on the FDA" claims, and patients appealed. The United States Court of Appeals for the Third Circuit, 159 F.3d 817, reversed. Certiorari was granted, and the Supreme Court, Chief Justice Rehnquist, held that patients' state law "fraud on the FDA" claims were impliedly preempted by the Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Device Amendments (MDA).

Court of Appeals reversed.

Justice Stevens filed opinion concurring in the judgment, in which Justice Thomas, J., joined.

**1013 *Syllabus* *

Respondent represents plaintiffs claiming injuries caused by the use of orthopedic bone screws in the pedicles of their spines. Petitioner assisted the screws' manufacturer in securing approval for the devices from the Food and Drug Administration (FDA or Administration), which has regulatory authority under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Devices Amendments of 1976(MDA). While the screws are in a class that normally must go through a time-consuming process to receive premarket approval (PMA), they were approved under an exception, known as the § 510(k) process, for predicate devices-devices that were already on the market when the MDA was enacted-and for devices that are "substantially equivalent" to predicate devices. The § 510(k) application filed by petitioner and the manufacturer sought clearance to market the screws for use in arm and leg bones, not the spine. Claiming that the FDA would not have approved the screws had petitioner not made fraudulent representations regarding their intended use, plaintiffs sought damages under state tort law. The District Court dismissed these fraud-on-the-FDA claims on, *inter alia,* the ground that they were pre-empted by the MDA. The Third Circuit reversed.

Held: The plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, the **1014 FDCA, as amended by the MDA. Pp. 1017-1020.

(a) The relationship between a federal agency and the entity it regulates is inherently federal because it originates from, is governed by, and terminates according to federal law. Because petitioner's FDA dealings were prompted by the MDA and the very subject matter of petitioner's statements were dictated by that statute-and in contrast to situations implicating "federalism concerns and the historic primacy of state regulation of [health and safety matters]," *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700-no presumption against pre-emption obtains in this case. The conflict here stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and the Administration uses this authority to achieve a delicate balance of statutory objectives that can be skewed by allowing state-law fraud-on-the-FDA claims. While the § 510(k) ***342** process lacks the PMA review's rigor, the former does set forth a comprehensive scheme for determining substantial equivalence with a predicate device. Other provisions give the FDA enforcement options that allow it to make a measured response to suspected fraud upon the Administration. This flexibility is a critical component of the framework under which the FDA pursues its difficult (and often competing) objectives of regulating medical device marketing and distribution without intruding upon decisions committed by the FDCA to health care professionals. Pp. 1017-1018.

(b) State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. Complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants, who might be deterred from seeking approval of devices with potentially beneficial off-label uses-an accepted medical practice in which a device is used for some other purpose than that for which the FDA approved it-for fear of being exposed to unpredictable civil liability. Conversely, applicants' fear that their disclosures to the FDA will later be judged insufficient in state court might lead them to submit information that the Administration neither needs nor wants, thus delaying the comparatively speedy § 510(k) process, and, in turn, impeding competition and delaying the prescription of appropriate off-label uses. Respondent's reliance on *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 104 S.Ct. 615, 78 L.Ed.2d 443, is misplaced. *Silkwood* was based on traditional state tort law principles, not on a fraud-on-the-agency theory, and, unlike *Silkwood,* there is clear evidence here that Congress intended that the MDA be enforced exclusively by the Federal Government. In addition, the MDA's express pre-emption provision does not bar the ordinary working of conflict pre-emption principles. *Geier v. American Honda Motor Co.,* 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914. And although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not stand for the proposition that any FDCA violation will support a state-law claim. Pp. 1018-1020.

159 F.3d 817, reversed.

REHNQUIST, C.J., delivered the opinion of the Court, in which O'CONNOR, SCALIA, KENNEDY, SOUTER, GINSBURG, and BREYER, JJ., joined. STEVENS, J., filed an opinion concurring in the judgment, in which THOMAS, J., joined, *post,* p. 1020.

Attorneys and Law Firms

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****1015** Michael D. Fishbein, Levin Fishbein Sedran & Berman, Philadelphia, PA, for respondent.

Opinion

Chief Justice REHNQUIST delivered the opinion of the Court.

Respondent represents plaintiffs who claim injuries resulting from the use of orthopedic bone screws in the pedicles of their spines. Petitioner is a consulting company that assisted the screws' manufacturer, AcroMed Corporation, in navigating the federal regulatory process for these devices. Plaintiffs say petitioner made fraudulent representations to the Food and Drug Administration (FDA or Administration) in the course of obtaining approval to market the screws. Plaintiffs further claim that such representations were at least a "but for" cause of injuries that plaintiffs sustained from the implantation of these devices: Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured. Plaintiffs sought damages from petitioner under state tort law. We hold that such claims are pre-empted by the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976(MDA), 90 Stat. 539, 21 U.S.C. § 301 (1994 ed. and Supp. V).

I

Regulation of medical devices is governed by the two Acts just named. The MDA separates devices into three categories: Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices "presen[t] a potential unreasonable risk of illness or injury" and therefore incur the FDA's strictest regulation. § 360c(a)(1)(C)(ii)(II). It is not disputed that the bone screws manufactured by AcroMed are Class III devices.

Class III devices must complete a thorough review process with the FDA before they may be marketed. This premarket approval (PMA) process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe ... [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." §§ 360e(d)(2)(A), (B). Among other information, an application must include all known reports pertaining to the device's safety and efficacy, see § 360e(c)(1)(A); "a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device," § 360e(c)(1)(B); "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device," § 360e(c)(1)(C); samples of the device (when practicable), see § 360e(c)(1)(E); and "specimens of the labeling proposed to be used for such device," § 360e(c)(1)

(F). The PMA process is ordinarily quite time consuming because ***345** the FDA's review requires an "average of 1,200 hours [for] each submission." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 477, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (citing Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987); Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 Food Drug Cosm. L.J. 510, 512-514 (1984)).

An exception to the PMA requirement exists for devices that were already on the market prior to the MDA's enactment in 1976. See 21 U.S.C. § 360e(b)(1)(A). The MDA allows these "predicate" devices to ****1016** remain available until the FDA initiates and completes the PMA process. In order to avoid the potentially monopolistic consequences of this predicate-device exception, the MDA allows other manufacturers to distribute (also pending completion of the predicate device's PMA review) devices that are shown to be "substantially equivalent" to a predicate device. § 360e(b)(1)(B).

Demonstrating that a device qualifies for this exception is known as the "§ 510(k) process," which refers to the section of the original MDA containing this provision. Section 510(k) submissions must include the following: "Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 CFR § 807.87(e) (2000); "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "[a]ny additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially ***346** equivalent to a device in commercial distribution," § 807.87(*l*).

In 1984, AcroMed sought § 510(k) approval for its bone screw device, indicating it for use in spinal surgery. See *In re Orthopedic Bone Screw Products Liability Litigation,* 159 F.3d 817, 820 (C.A.3 1998). The FDA denied approval on the grounds that the Class III device lacked substantial equivalence to a predicate device. See *ibid.* In September 1985, with the assistance of petitioner, AcroMed filed another § 510(k) application. "The application provided additional information about the ... device and again indicated its intended use in spinal surgery. The FDA again rejected the application, determining that the device was not substantially equivalent to a predicate device and that it posed potential risks not exhibited by other spinal-fixation systems." *Ibid.* In December 1985, AcroMed and petitioner filed a third § 510(k) application.

> "AcroMed and [petitioner] split the ... device into its component parts, renamed them 'nested bone plates' and '[cancellous] bone screws' and filed a separate § 510(k) application for each component. In both applications, a new intended use was specified: rather than seeking clearance for spinal applications, they sought clearance to market the plates and screws for use in the long bones of the arms and legs. AcroMed and Buckman claimed that the two components were substantially equivalent to predicate devices used in long bone surgery. The FDA approved the devices for this purpose in February 1986." *Ibid.*

Pursuant to its designation by the Judicial Panel on Multidistrict Litigation as the transferee court for *In re Orthopedic Bone Screw Liability Litigation,* MDL No. 1014, the District Court for the Eastern District of Pennsylvania has been the recipient of some 2,300 civil actions related to these medical devices. Many of these actions include state-law ***347** causes of action claiming that petitioner and AcroMed made fraudulent representations to the FDA as to the intended use of the bone screws and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment. The District Court dismissed these "fraud-on-the-FDA" claims, first on the ground that they were expressly pre-empted by the MDA, and then, after our decision in *Medtronic,* on the ground that these claims amounted to an improper assertion of a private right of action under the MDA. [1] See 159 F.3d, at 821.

****1017** A divided panel of the United States Court of Appeals for the Third Circuit reversed, concluding that plaintiffs' fraud claims were neither expressly nor impliedly pre-empted. We granted certiorari, 530 U.S. 1273, 120 S.Ct. 2739, 147 L.Ed.2d 1004 (2000), to resolve a split among the Courts of Appeals on this question, see *Kemp v. Medtronic, Inc.,* 231 F.3d 216, 233-236 (C.A.6 2000) (identifying split and holding such claims expressly pre-empted), and we now reverse.

II

[1] [2] [3] Policing fraud against federal agencies is hardly "a field which the States have traditionally occupied," *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action. To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. Cf. *Boyle v. United Technologies Corp.,* 487 U.S. 500, 504-505, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988) (allowing pre-emption of state law by federal common law where the interests at stake are "uniquely federal" in nature). Here, petitioner's dealings with the FDA were prompted by the MDA, and the very subject matter ***348** of petitioner's statements were dictated by that statute's provisions. Accordingly-and in contrast to situations implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety," *Medtronic,* 518 U.S., at 485, 116 S.Ct. 2240-no presumption against pre-emption obtains in this case.

Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. [2] The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

As described in greater detail above, the § 510(k) process sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device. Among other information, the applicant must submit to the FDA "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 CFR § 807.87(e) (2000), and a statement attesting to and explaining the similarities to and/or differences from similar devices (along with supporting data), see § 807.87(f). The FDA is also empowered to require additional necessary information. See § 807.87(*l*). Admittedly, the § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device. Nevertheless, to achieve its limited purpose, the § 510(k) process imposes upon applicants a variety of requirements that are designed to enable the FDA to ***349** make its statutorily required judgment as to whether the device qualifies under this exception.

Accompanying these disclosure requirements are various provisions aimed at detecting, deterring, and punishing false statements made during this and related approval processes. The FDA is empowered to investigate suspected fraud, see ****1018** 21 U.S.C. § 372; 21 CFR § 5.35 (2000), and citizens may report wrongdoing and petition the agency to take action, § 10.30. In addition to the general criminal proscription on making false statements to the Federal Government, 18 U.S.C. § 1001 (1994 ed., Supp. V), [3] the FDA may respond to fraud by seeking injunctive relief, 21 U.S.C. § 332, and civil penalties, 21 U.S.C. § 333(f)(1)(A); seizing the device, § 334(a)(2)(D); and pursuing criminal prosecutions, § 333(a). The FDA [4] thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration.

This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives. For example, with respect to Class III devices, the FDA simultaneously maintains the exhaustive PMA and the more limited § 510(k) processes in order to ensure both that medical devices are ***350** reasonably safe and effective and that, if the device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time. Similarly, "off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. See, *e.g.,* Beck & Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 76-77 (1998) (noting that courts, several States, and the "FDA itself recogniz[e] the value and propriety of off-label use"). Indeed, a recent amendment to the FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (1994 ed., Supp. V). Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.

State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability. In effect, then, fraud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA ***351** expressly disclaims any intent to directly regulate the practice of medicine, see ****1019** 21 U.S.C. § 396 (1994 ed., Supp. V), and even though off-label use is generally accepted. [5]

Conversely, fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application. As a result, the comparatively speedy § 510(k) process could encounter delays, which would, in turn, impede competition among predicate devices and delay health care professionals' ability to prescribe appropriate off-label uses. [6]

Respondent relies heavily on *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984), which it reads to "creat[e] a virtually irrefutable presumption against implied preemption of private damage remedies predicated on an alleged conflict with a federal remedial scheme." Brief for Respondent 34. ***352** *Silkwood* is different from the present case, however, in several respects. Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant. See 464 U.S., at 241, 104 S.Ct. 615. Moreover, our decision there turned on specific statutory evidence that Congress "disclaimed any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials." *Id.*, at 257, 104 S.Ct. 615. In the present case, by contrast, we have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government. 21 U.S.C. § 337(a).

[4] Respondent also suggests that we should be reluctant to find a pre-emptive conflict here because Congress included an express pre-emption provision in the MDA. See Brief for Respondent 37. To the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last Term in *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000), that neither an express pre-emption provision nor a saving clause "bar[s] the ordinary working of conflict pre-emption principles." *Id.*, at 869, 120 S.Ct. 1913.

We must also reject respondent's attempt to characterize both the claims at issue in *Medtronic* (common-law negligence action against the manufacturer of an allegedly defective pacemaker lead) and the fraud claims here as "claims arising from violations of FDCA requirements." Brief for Respondent 38. Notwithstanding the fact that *Medtronic* did not squarely ****1020** address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. See 518 U.S., at 481, 116 S.Ct. 2240. In the present case, ***353** however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.

The judgment of the Court of Appeals is reversed.

It is so ordered.

Justice STEVENS, with whom Justice THOMAS joins, concurring in the judgment.

As the Court points out, an essential link in the chain of causation that respondent must prove in order to prevail is that, but for petitioner's fraud, the allegedly defective orthopedic bone screws would not have reached the market. The fact that the Food and Drug Administration (FDA) has done nothing to remove the devices from the market, even though it is aware of the basis for the fraud allegations, convinces me that this essential element of the claim cannot be proved. I therefore agree that the case should not proceed. [1]

***354** This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims.

If the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme. Cf. *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 495, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (holding that the presence of a state-law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but "merely provides another reason for manufacturers to comply with ... federal law"); *id.,* at 513, 116 S.Ct. 2240 (O'CONNOR, J., concurring in part and dissenting in part) (same). [2]

****1021 *355** Under the pre-emption analysis the Court offers today, however, parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process. I do not believe the reasons advanced in the Court's opinion support the conclusion that Congress intended such a harsh result. Cf. *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984) (declining to infer that a federal statutory scheme that affords no alternative means of seeking redress pre-empted traditional state-law remedies). For that reason, although I concur in the Court's disposition of this case, I do not join its opinion.

All Citations

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Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,* 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 The District Court also determined that the plaintiffs' fraud claims failed for lack of proximate cause, see *In re Orthopedic Bone Screw Products Liability Litigation,* 159 F.3d 817, 821 (C.A.3 1998), but that question is not presently before us.

2 In light of this conclusion, we express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k.

3 Title 18 U.S.C. § 1001(a) (1994 ed., Supp. V) provides: "[W]hoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; [or] makes any materially false, fictitious or fraudulent statement or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry; shall be fined under this title or imprisoned not more than 5 years, or both."

4 The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

5 See Green & Schultz, Tort Law Deference to FDA Regulation of Medical Devices, 88 Geo. L.J. 2119, 2133 (2000) ("Physicians may prescribe drugs and devices for off-label uses"); Smith, Physician Modification of Legally Marketed

Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act, 55 Food & Drug L.J. 245, 251-252 (2000) (discussing off-label use in terms of the "practice of medicine doctrine[, which] stands firmly for the proposition that regulatory efforts are directed primarily at device marketing by manufacturers, not device use by physicians"); Beck & Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize").

6 In light of the likely impact that the fraud-on-the-FDA claims would have on the administration of the Administration's duties, we must reject respondent's contention that these claims "will ... affect only the litigants and will not have the kind of direct impact on the United States, which preemption is designed to protect from undue incursion." Brief for Respondent 30 (citing *Miree v. DeKalb County,* 433 U.S. 25, 97 S.Ct. 2490, 53 L.Ed.2d 557 (1977)).

1 Though my analysis focuses on the failure of the plaintiffs to establish a necessary element of their claim, that failure is grounded not in the minutiae of state law but in the details of the federal regulatory system for medical devices. Therefore, while this case does not fit neatly into our pre-existing pre-emption jurisprudence, it is accurate, in a sense, to say that federal law "pre-empts" this state-law fraud-on-the-FDA claim because the FDA has not acknowledged such a fraud and taken steps to remove the device from the market.

2 Though the United States in this case appears to take the position that fraud-on-the-FDA claims conflict with the federal enforcement scheme even when the FDA has publicly concluded that it was defrauded and taken all the necessary steps to remove a device from the market, see Brief for United States as *Amicus Curiae* 24, 30, that has not always been its position. As recently as 1994, the United States took the position that state-law tort suits alleging fraud in FDA applications for medical devices do not conflict with federal law where the FDA has "subsequently concluded" that the device in question never met the appropriate federal requirements and "initiated enforcement actions" against those responsible for fraudulently obtaining its approval. Brief for United States as *Amicus Curiae* in *Talbott v. C.R. Bard, Inc.,* No. 94-1951(CA1), reprinted in App. to Pet. for Cert. in *Talbott v. C.R. Bard., Inc.,* O.T.1995, No. 95-1321, p. 84a.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Boston Scientific Corporation and Asthmatx, Inc.	)	
Opposers,	)	
v.	)	Opposition No. 91215699
Holaira, Inc.	)	
Applicants.	)	

CERTIFICATE OF SERVICE BY MAIL

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

Elizabeth K. McDermott, of the City of Minneapolis, County of Hennepin, in the State of Minnesota, states that on the 2nd day of December, 2015, she mailed by First Class mail, a true and correct copy of:

1) Opposers' Confidential Trial Brief;
2) Opposers' Non-Confidential Trial Brief;
3) Opposers' Confidential Reply in Support of Objections to Applicant's Evidence and Opposers' Confidential Response to Applicant's Evidentiary Objections
4) Opposers' Non-Confidential Reply in Support of Objections to Applicant's Evidence and Opposers' Non-Confidential Response to Applicant's Evidentiary Objections; and
5) Appendix.

in the above-captioned action to the following last known address of record for Applicant, to-wit:

Barbara J. Grahn
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